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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/667,796	09/22/2000	Wayne R. Curtis	99-2175	9738
7590 10/30/2003				
Intellectual Property Office The Pennsylvania State University 113 Technology Center University Park, PA 16802			EXAMINER FOX, DAVID T	
			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 10/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/667,796	CURTIS, WAYNE R.	
	Examiner	Art Unit	
	David T. Fox	1638	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 15-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendments and arguments of 10 July 2003 have overcome the following rejections: the indefiniteness rejections, the anticipation rejection of claim 2 over Gomord et al, and the obviousness rejections of claim 10.

Claims 1-12 and 15-20 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method for transforming dicotyledonous cells or hairy root cultures via the utilization of an auxotrophic strain of Agrobacterium, does not reasonably provide enablement for claims broadly drawn to monocot transformation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims, as stated on page 2 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant refers to Narasimhulu et al to rebut the rejection. However, this reference was not received by the Examiner.

Claims 1, 3, 5-7, 11, 16 and 18 remain rejected under 35 U.S.C. 102(b) as being anticipated by Gomord et al, as stated on pages 3-4 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that Gomord et al do not teach large volumes of cultured cells, and ultimately teach protein recovery from solid medium. The Examiner maintains that the rejected claims do not specify a particular volume of cells, and that

the reference does in fact teach all of the claimed steps. It is irrelevant that the reference also teaches the later isolation of protein from cells cultured on solid medium, particularly given the open language of the claims.

Claims 1-3, 5-8, 11-12 and 15-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gomord et al taken with Hiei et al, as stated on pages 4-6 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that Gomord et al is not combinable with Hiei et al because the scale-up of liquid culture would result in *Agrobacterium* overtaking the culture, and because Hiei et al does not teach a method for transient transformation. The Examiner maintains that the claimed time frame of 1-4 days would result in stable transformation, and that Gomord et al clearly suggest the transformation of monocots for the production of heterologous proteins, as stated in the last Office action.

Regarding the allegedly unexpected results of the *Agrobacterium* not overtaking the liquid culture, the Examiner notes that these results were only obtained when using a slower-growing auxotrophic *Agrobacterium* strain of a particular type (see page 12 of the amendment of 10 July 2003, middle paragraph). In contrast, only claim 10 is so limited.

See *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983) which teach that the evidence of nonobviousness should be commensurate with the scope of the claims.

Claims 1-3, 5-7, 9, 11 and 15-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gomord et al taken with Sastry et al, as stated on pages 6-7 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that Sastry et al fail to teach the use of particular types of *Agrobacterium* auxotrophs in a plant cell bioreactor. Applicant is referred to *Lindner* cited above.

Claims 1-2, 4-7, 11-12 and 15-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Gomord et al taken with Wongsamuth et al, as stated on pages 7-8 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that the references are not properly combinable because Wongsamuth et al teach stable genetic transformation. The Examiner maintains that the claimed time frame encompasses stable transformation, and that the general suggestion of Gomord et al to widely apply their technique provides the motivation to combine the teachings of the references.

Claims 1-9, 11-12 and 15-18 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al, as stated on page 8 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that Goodman et al do not teach the particular types of monitoring as claimed, and that Goodman et al do not teach that recombinant polypeptide is obtained from the culture of plant cells or tissue. The Examiner maintains

that the claims are not limited to a single means of monitoring, and that Goodman et al do in fact teach recombinant protein production from cultured plant tissues. Choice of solid or liquid medium appears to have been an optimization of process parameters, in the absence of evidence to the contrary. See also *Lindner* cited above.

Regarding the recovery of the protein from the culture medium versus the plant cells themselves, note that claim 1 recites that the polypeptide is recovered from the cells or tissue, not the liquid medium (see step v). See also page 32 of the specification, lines 16-19 which state that the protein may be recovered from either the liquid medium or the cultured cells.

Claims 1, 13 and 19-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Goodman et al taken with Baszczyński et al, as stated on page 8 of the last Office action.

Applicant's arguments filed 10 July 2003 have been fully considered but they are not persuasive. Applicant urges that Baszczyński et al do not teach transient transformation. The Examiner maintains that the claimed time frame encompasses stable transformation, as is well-known in the art.

Claim 10 is deemed free of the prior art, given the failure of the prior art to teach or suggest the use of the particularly claimed type of *Agrobacterium* auxotroph in a bioreactor of liquid medium for the culture of plant cells which transiently produce a heterologous protein of interest.

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached on (703) 306-3218. The fax phone number for this Group is (703) 872-9306. The after final fax phone number is (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

October 24, 2003

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180-1638

